REMARKS

Claims 1-3, 5-10, 12, and 14-19 are pending. Claims 4, 11, and 13 are cancelled without prejudice or disclaimer. Claims 3, 5, 8, 10 and 12 are amended for clarity and/or to correct dependencies. New claims 14-16 and 17-19 are added to correct multiple dependencies of claims 10 and 12, respectively. Therefore, no new matter has been added. The Office Action is discussed below:

Claim Rejection Under 35 USC § 112, second paragraph:

On page 2 of the office action, the examiner has rejected claims 4 and 13 and alleged as being indefinite. Without acquiescing to the rejections, in order to expedite the prosecution, applicants cancel claims 4 and 13 without prejudice or disclaimer.

Claim Objection:

On page 2 of the office action, the examiner has objected to claim 11 and alleged as being substantially duplicate of claims 1-5. Without acquiescing to the rejections, in order to expedite the prosecution, applicants cancel claim 11 without prejudice or disclaimer.

Claim Rejection Under 35 USC § 112, first paragraph:

On pages 3-4 of the office action, the examiner has rejected claim 12 and alleged as being non-enabling for using the term "preventing." Without acquiescing to the rejections, in order to expedite the prosecution, applicants amend claim 12 by deleting the term "preventing."

Withdrawal of the enablement rejection is therefore requested.

Claim Rejection under USC § 102

On pages 4-5 of the office action, the examiner has rejected claims 1-11 and alleged as being anticipated by Ohtsuka et al. (US 6,372,735). The examiner has referred to the compound of Example 20 of Ohtsuka et al. and a process of producing

the same (see Ohtsuka et al., col. 42, line 15 to col. 43 line 34 and col. 54, lines 1-39) and alleged that Ohtsuka et al. disclosed the claimed compound. Applicants respectfully disagree with the examiner and submit that:

In order to reject a claim under 35 USC § 102, the examiner must demonstrate that each and every claim term is contained in a single prior art reference. *See Scripps Clinic & Research Foundation v. Genentech, Inc.*, 18 USPQ2d 1001, 1010 (Fed. Cir. 1991); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 231 USPQ 81, 90 (Fed. Cir. 1986); *see also* MPEP § 2131 (Rev. 2, May 2004).

Applicants provide the following explanations to assist the Examiner in distinguishing the cited reference:

Ohtsuka et al. discloses a "crystalline compound" (see Ohtsuka et al., col. 42, line 15 to col. 43 line 34). In contrast, the claimed compound is an "amorphous compound", which exhibits improved solubility in water compared to the "crystalline compound" of the cited art (see specification, for example, page 5, lines 17 to 21). Therefore, the Ohtsuka does not anticipate the claimed compound.

Applicants further state that while Ohtsuka discloses a "crystalline form" of the "compound A," and not an "amorphous form" of the "compound A". The instant specification provides a Comparative Example with respect to the crystalline form and the amorphous form of the "compound A." As described in the specification (see for example, page 9, line 36 to page 10, line 6), the crystalline compound of Comparative Example 1 was produced according to the Example 20 of Ohstuka and purified by re-crystallization, which is a conventional purification method (see Ohtsuka et al., col. 13, lines 30-32 and col. 14, lines 41-43). When the crystalline compound was subjected to a re-crystalline process, a crystalline form was present. The crystalline compound A exhibited characteristic X-ray diffraction peaks. On the other hand, the compounds of Examples 1 and 2 show no specific peak indicating that the claimed compounds are amorphous (see instant Figure 1, for example).

According to the claimed invention, the amorphous compound A exhibits improved solubility in water compared with crystalline compound A (see specification,

for example, page 5, lines 17 to 21). This was demonstrated by Test Examples 2 to 4 (see specification, for example, page 13, line 6 to page 16, line 20). Therefore, the claimed amorphous compound A is not described in Ohsuka.

On page 5 of the office action, the examiner finally concluded that the applicants "must prove that the prior art process does not produce their compound." In response, applicants point out that the Ohtsuka process does not disclose the steps to produce the claimed amorphous compounds (see specification, for example, page 4, line 25 to page 5, line 16). Therefore, the Ohtsuka process does not produce the claimed "amorphous compounds." Withdrawal of the anticipation rejection is solicited.

REQUEST

In view of above amendments and remarks, applicants respectfully submit that claims 1-3, 5-10, and 12 are allowable, and respectfully request favorable consideration to that effect. The Examiner is invited to contact the undersigned at (202) 912-2000 should there be any questions.

Respectfully submitted,

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Date

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